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PATENT
Docket No.: 54404US008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: RAYMOND P JOHNSTON, MATTHEW T. SCHOLZ, STEVEN B.
HEINECKE AND CHARLES A. HENTZEN

Application No.: 09/961,091 Group Art Unit: 3761

Filed: January 14, 2002 Examiner: K. Lewis

Title: MEDICAL ARTICLE HAVING A FLUID CONTROL FILM

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APPEAL BRIEF

Applicants filed a Notice of Appeal in this application on April 6, 2004 from the final rejections set forth in the Office Action dated October 7, 2003. Applicants filed a Response under 37 CFR § 1.116 on November 10, 2003. Because no Advisory Action was mailed in reply to Applicants' Response, which was filed within two months of the final Office Action, the Notice of Appeal was timely filed within the shortened statutory period.

This Appeal is proper because the present application includes claims that have been finally rejected. Applicants' Brief in support of this Appeal follows.

REAL PARTY IN INTEREST

The real party in interest in this Appeal is 3M Innovative properties Company, the assignee of all rights to the invention disclosed in the subject application. An assignment of the inventors' rights to Minnesota Mining and Manufacturing Company was recorded in the United States Patent and trademark Office on March 22, 1999 at Reel 9840, Frame 0880. Subsequently an assignment from Minnesota Mining and Manufacturing Company to 3M Innovative Properties Company was recorded in the

United States Patent and trademark Office on May 22, 2001 at Reel 11596, Frame 0092.

RELATED APPEALS AND INTERFERENCES

There are no known appeals or interferences related to this Appeal.

STATUS OF THE CLAIMS

The present application is a continuation of United States Patent Application Serial Number 09/235,720, filed January 22, 1999, entitled "MEDICAL ARTICLE HAVING A FLUID CONTROL FILM" which has issued as United States Patent Number 6,420,622.

The present application was filed with a Preliminary Amendment that canceled claims 1-35 and introduced claims 36-60. Claims 36-60 stand rejected in the final Office Action dated October 7, 2003. Accordingly, claims 36-60 are the subject of this Appeal. A copy of the pending claims is provided in the Appendix attached hereto.

STATUS OF AMENDMENTS

No claim amendments have been presented after final rejection.

SUMMARY OF THE INVENTION

The present invention is a medical article that includes a fluid control film component that permits transport of fluid between a medical treatment site and a remote area. The fluid control film component includes a microstructure-bearing surface with a plurality of channels, which facilitate the transport of fluid between the medical treatment site and the remote area. The present invention also provides a method for using the medical article to transport fluid between a medical treatment site and a remote area. Appealed claims 36-50 are directed to the novel medical article. Appealed claims 51-60 are directed to the method.

The fluid control film component of the medical article permits the transport of fluid between a medical treatment site such as, for example, a wound, a surgical incision, and the like, and a remote area such as, for example, a reservoir or absorbent material. In the case of surgical drape articles, the article can control or transport fluids

emanating from a surgical site. In the case of medical treatment articles (e.g., wound dressings), the article can keep the wound area at a preferred moisture level, transport fluid between the wound site and a remote area, or deliver a medicament to a wound site (specification, page 4, lines 15-24).

The fluid control film component of the article includes capillary channels that are formed from a polymeric film layer having a microstructured surface (specification, page 8, lines 8-16). Figure 6 illustrates some exemplary configurations of capillary channels in the fluid control film.

The fluid control film may be incorporated to transport a fluid to a remote site (e.g., facilitate wicking of a fluid away from an operating site and out of the way of the surgeon), deliver a fluid to a site (e.g., facilitate delivery of a medicament or flushing solution to a surgery site), or absorb or contain excess wound exudate. Thus, the medical article can, for example, assist in removing fluid from a surgical site, out of the way of the surgeon, during a medical procedure.

In other embodiments, the fluid control film may be incorporated to provide the advantages described above, and/or disperse the fluid over an increased surface area to promote more rapid evaporation (e.g., through a high MVTR film). Dressings incorporating a fluid control film may be fabricated to accommodate wounds of all types including, for example, burns, abrasions, surgical wounds, and lacerations. Furthermore, the fluid control film component of such dressing also may be fabricated of material translucent enough to permit visual inspection of the wound while the dressing is in place. This is in contrast to conventional wound dressings that place an absorbent material over the wound. A medical article of the invention can permit draining exudate from a wound site while also providing one or more additional benefits such as, for example, improved evaporation of the exudate, allowing visual inspection of the wound (e.g., when the fluid control film is suitable transparent), and removal of the exudate from the wound site (specification, page 5, line 1 through page 6, line 5).

Another feature of the present invention is that the medical article may facilitate delivery of fluid to a medical treatment site. One or more medicaments may be stored at the remote area and be transported via the fluid control film to the medical treatment site (specification, page 6, lines 6-8).

ISSUES ON APPEAL

Claims 36-39, 41-44, 46, 48, 51-55, and 58 stand rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,514,120 to Johnston *et al.* (“Johnston ‘120”).

Claims 47, 49, 50, 56, 57, 59, and 60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnston ‘120.

In view of these rejections, the issues on appeal are:

- A. Whether claims 36-39, 41-44, 46, 48, 51-55, and 58 are patentable under U.S.C. § 102(b) over Johnston ‘120.
- B. Whether claims 47, 49, 50, 56, 57, 59, and 60 are patentable under 35 U.S.C. § 103(a) over Johnston ‘120.
- C. Whether claims 40 and 45 are patentable over Johnston ‘120.

GROUPING OF CLAIMS

Applicants contend, for the purposes of this Appeal only, that the appealed claims fall into the following groups:

For the rejection under 35 U.S.C. § 102(b) over Johnston ‘120, claims 36, 38, 39, 41-44, 48, and 51-55 stand or fall as one group; each of claims 37, 46, and 58 stands or falls independently.

For the rejection under 35 U.S.C. § 103(a) over Johnston ‘120, claims 49, 50, 59, and 60 stand or fall as one group; claims 47, 56, and 57 stand or fall as a second group.

ARGUMENT

A. Claims 36-39, 41-44, 46, 48, 51-55, and 58 are patentable under U.S.C. § 102(b) over Johnston ‘120.

Claims 36-39, 41-44, 46, 48, 51-55, and 58 stand rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,514,120 to Johnston *et al.* (“Johnston ‘120”).

Claim 36 is directed to a medical treatment article and recites three elements: i) at least one fluid control film component; ii) having at least one microstructure-bearing surface with a plurality of channels therein; iii) that permit transport of fluid between a medical treatment site and a remote area. Claims 37 and 46 depend from claim 36, each reciting additional elements that patentably distinguish the invention over Johnston '120. Claims 38, 39, 41-44, and 48 also depend from claim 36.

Claim 51 is directed to a method of using a medical article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area. The method includes the steps of: placing the medical article in proximity to a medical treatment site so that the fluid control film component is capable of providing fluid communication between the medical treatment site and the remote area; and allowing the medical treatment article to transport fluid between the medical treatment site and the remote area. Claim 58 depends from claim 51 and recites additional elements that patentably distinguish the invention over Johnston '120. Claims 52-55 also depend from claim 51.

Johnston '120 reports an absorbent article that comprises an absorbent core and at least one liquid management member in contact with the absorbent core, which comprises a film having at least one microstructure-bearing hydrophilic surface that promotes rapid directional spreading of liquids (Abstract). The liquid management member disperses fluid throughout the absorbent article from, for example, a location where liquid is expected to be introduced into the article (col. 6, lines 48-55). In this way, the absorbent article effectively increases the volume of fluid that can be retained within the article before a portion of the absorbent article becomes saturated with fluid and begins to leak. For this reason, the liquid management member is preferred to be substantially coextensive with the absorbent core, i.e., extend to within about 1 to 2 centimeters of the edge of the absorbent core (col. 7, lines 61-64). It is also typically preferred that the liquid management member not extend beyond the absorbent core, as this may cause the absorbent article to leak (col. 7, lines 64-66).

The Office Action asserts that Johnston '120 discloses all of the claimed elements of the present invention.

1. Johnston '120 Does Not Teach or Suggest Each and Every Limitation of the Claimed Invention.

M.P.E.P. § 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Claim 36 recites a medical treatment article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and *a remote area*. (emphasis added).

Claim 51 recites method of using a medical article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and *a remote area*, the method comprising (a) placing the medical article in proximity to a medical treatment site so that the fluid control film component is capable of providing fluid communication between the medical treatment site and the *remote area*; and (b) allowing the medical treatment article to transport fluid between the medical treatment site and the *remote area*. (emphasis added).

Specifically, Applicants submit that Johnston '120 fails to disclose (a) articles that permit fluid transport to a remote area, as required by claim 36, or (b) methods that include fluid transport to a remote area, as required by claim 51.

Exemplary articles, and exemplary configurations of the remote area, are described in Applicants' disclosure from page 30, line 20 through page 35, line 24, and illustrated in Figs. 2a-2j. The consistent theme throughout all of these embodiments is the remote area is spatially removed from the medical treatment site to some extent; the extent to which the remote area is removed from the medical treatment site can vary somewhat according to the particular embodiment of the article. In other words, the fluid control film component extends beyond the boundary of the remote area – in some cases, an absorbent material – in order to direct fluid transport into or out of the remote area and between the remote area and the medical treatment site.

In contrast, Johnston '120 teaches the use of a fluid management member to transport fluid within an absorbent core. The liquid management member is preferred

to be substantially coextensive with the absorbent core and not extend beyond the absorbent core, as this may cause the absorbent article to leak. Thus, Johnston '120 teaches away from articles and methods recited in the appealed claims.

The patentability of this feature of the medical article was acknowledged in the parent of the present application – U.S. Ser. No. 09/235,720, now U.S. Patent No. 6,420,622 (“the ‘622 patent”). Claim 1 of the ‘622 patent reads, in part:

“...while allowing for fluid transfer along the plurality of channels between the medical treatment site and the fluid reservoir positioned remote from the medical treatment site.”

(col. 27, lines 59-62).

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Johnston '120 on the very same basis as the claims presently under appeal. Claim 1 in the parent application was ultimately allowed without amendment after Applicants explained that Johnston '120 fails to disclose articles and methods including fluid transport *to a remote area* – recited in claim 1 of the ‘622 patent as “the fluid reservoir positioned remote from the medical treatment site.” In an interview summary relating to a telephonic interview conducted June 4, 2001, the Examiner stated,

“Applicant’s representative stated that Johnston et al. [U.S. Patent No. 5,514,120] did not disclose ‘a fluid reservoir including absorbent material positioned remote from the fluid handling portion.’ The examiner reviewed the Johnston et al. reference and agreed with Applicant’s representative arguments.”

The Notice of Allowance included the following statement in the Reason for Allowance:

“....Johnston et al. further disclose the management member as having a fluid reservoir including an absorbent article. Johnston et al. *fail to teach the absorbent member is positioned remote from the fluid handling portion* to permit fluid transfer between the absorbent material and the end portion of the fluid control film.” (emphasis added).

Each of claims 36 and 51 recites the limitation of fluid transport between the medical treatment site and the remote area – the very same concept that was acknowledged in the parent case to be absent from the teachings of Johnston '120.

Consequently, Applicants submit that Johnston '120 cannot anticipate either claim 36 or claim 51.

Applicants acknowledge that the appealed claims are somewhat broader than the claims of the '622 patent, but Applicants submit that the broader scope does not impact the patentability of the appealed claims. The "remote area" of the presently appealed claims is broader than the fluid reservoir recited in the '622 patent because the fluid reservoir of the '622 patent includes an absorbent material while the remote area recited in the appealed claims does not require an absorbent material. Applicants submit that Johnston '120 fails to teach fluid transport to a non-absorbent remote area to at least the same extent that Johnston '120 has been acknowledged to fail to teach that the "absorbent member is positioned remote from the fluid handling portion to permit fluid transfer between the absorbent material and the end portion of the fluid control film."

The Final Office Action responds to Applicants' argument presented above by stating that "the subject matter discussed in the interview is not relevant since the claimed limitations of the present invention are different than the claimed limitations of the '720 application [the '622 patent]."

While certain limitations in the claims of the '622 patent and the appealed claims differ, the subject matter discussed in the interview is absolutely relevant because the limitation that established patentability of the claims of the '622 patent over Johnston '120 (i.e., fluid transport to a location remote from the medical treatment site) is the very same – even if presented in the '622 patent in the context of an article of narrower scope – as the limitation that establishes the patentability of the appealed claims over the very same Johnston '120 reference.

The Final Office Action continues to construe the Johnston '120 reference to anticipate the appealed claims, stating: "The examiner clearly points that 'the remote area' is being defined as the absorbent core, which is remote from a medical treatment site (a patient)." Applicants submit that this view misconstrues the actual teaching of Johnston '120. If Johnston '120 is to anticipate claim 36, then the fluid management member of Johnston '120 must transport fluid between a medical treatment site (the patient) and a remote area (the absorbent core), as recited in claim 36 and claim 51. It does not. The fluid management member of Johnston '120 does not transport fluid from the patient to the absorbent core. The liquid management member of Johnston '120 transports fluid

within the absorbent core *only after* the fluid has already been absorbed into the absorbent core.

Johnston '120 fails to teach each and every element set forth in claims 36 and 51 and, therefore, cannot anticipate these claims. Each of claims 38, 39, 41-44, and 48 depends from claim 36 and therefore contains all of the elements of claim 36. Thus, Johnston '120 cannot anticipate claims 38, 39, 41-44, and 48. Each of claims 52-55 depends from claim 51 and therefore contains all of the elements of claim 51. Thus, Johnston '120 cannot anticipate claims 52-55.

2. Claims 37, 46, and 58 Recite Additional Elements That Patentably Distinguish Embodiments of the Invention From Johnston '120.

Claim 37 depends from claim 36 and is directed to embodiments in which the article is a wound dressing, wound drain, tympanostomy fluid wick, intravenous access site dressing, drug delivery dressing, surgical drape, or sweat collection patch. As Johnston '120 does not teach the use of a fluid management member in a wound dressing, wound drain, tympanostomy fluid wick, intravenous access site dressing, drug delivery dressing, surgical drape, or sweat collection patch, Johnston '120 cannot anticipate claim 37.

Claim 46 depends from claim 36 and is directed to an embodiment in which the article is a combined wound dressing and wound drain. As Johnston '120 fails to teach the use of a fluid management member in a combined wound dressing and wound drain, Johnston '120 cannot anticipate claim 46.

Claim 58 depends from claim 51 and is directed to a method of transporting fluid between a medical treatment site and a remote area in which fluid is transported from the medical treatment site to the remote area and from the remote area to the medical treatment site. Because Johnston '120 does not teach bidirectional fluid transport in the fluid management member, Johnston '120 cannot anticipate claim 58.

For the reasons presented, claims 36-39, 41-44, 46, 48, 51-55, and 58 are patentable over Johnston '120, and Applicants respectfully request reversal of the rejections.

B. Claims 47, 49, 50, 56, 57, 59, and 60 are patentable under 35 U.S.C. § 103(a) over Johnston '120.

Claims 47, 49, 50, 56, 57, 59, and 60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnston '120.

1. Johnston '120 Does Not Teach or Suggest Each and Every Limitation of the Claimed Invention.

M.P.E.P. § 706.02(j) states that to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference(s) or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art reference must teach or suggest all of the claim limitations.

Applicants submit that Johnston '120 fails to teach or suggest all of the claim limitations of the appealed claims. Each of claims 47, 49, and 50 depend from claim 36 and therefore include all of the limitations of claim 36. Each of claims 56, 57, 59, and 60 depend from claim 51 and therefore include all of the limitations of claim 51. Specifically, Applicants submit that Johnston '120 fails to disclose (a) articles that permit fluid transport to a remote area, as required by claim 36 – and, therefore, also claims 47, 49, and 50, or (b) methods that include fluid transport to a remote area, as required by claim 51 – and, therefore, also claims 56, 57, 59, and 60.

Furthermore, no teaching or suggestion from Johnston '120 or otherwise known to one of ordinary skill in the art at the time the invention was made would have motivated one to modify Johnston '120 in a manner that would provide (a) articles that permit fluid transport to a remote area, or (b) methods that include fluid transport to a remote area

Thus, for at least all of the reasons presented above regarding the rejection of claims 36-39, 41-44, 46, 48, 51-55, and 58 under 35 U.S.C. § 102(b) as being anticipated by Johnston '120, Applicants submit that claims 47, 49, 50, 56, 57, 59, and 60 are patentable over Johnston '120.

2. Claims 47, 49, 50, 56, 57, 59, and 60 Recite Additional Elements That Patentably Distinguish Embodiments of the Invention From Johnston '120.

Claims 49, 50, 59, and 60 are directed to medical articles and methods in which the fluid control film component of the article permits visual inspection of the medical treatment site through at least a portion of the fluid control film component. In addition to the deficiencies of Johnston '120 presented above, Johnston '120 fails to teach or suggest absorbent articles in which a site of the user is visible through the fluid management member, claims 49, 50, 59, and 60 are patentable over Johnston '120.

Claims 47, 56, and 57 are directed to medical articles and methods in which the fluid control film component is used to deliver a medicament to a medical treatment site. Because Johnston '120 fails to teach the use of a fluid management member to deliver a fluid to a user, and further fails to teach delivery of a medicament to a user, claims 47, 56, and 57 are patentable over Johnston '120.

For the reasons presented, claims 47, 49, 50, 56, 57, 59, and 60 are patentable over Johnston '120, and Applicants respectfully request reversal of the rejections.

C. Claims 40 and 45 are patentable over Johnston '120.

No specific grounds for rejection of claims 40 and 45 were presented in the Final Office Action. However, because each of claims 40 and 45 depends from claim 36, Applicants submit that claims 40 and 45 are patentable under both 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) because, at the very least, Johnston '120 fails to teach or suggest all of the limitations of claims 40 and 45.

For the reasons presented, claims 40 and 45 are patentable over Johnston '120, and Applicants respectfully request reversal of the rejections.

CONCLUSION

Johnston '120 fails to teach or suggest all of the limitations recited in the appealed claims. Specifically, Johnston '120 fails to teach or suggest (a) articles that permit fluid transport to a remote area, or (b) methods that include fluid transport to a remote area. Accordingly, claims 36-60 are allowable over the art of record. Applicants respectfully request that the Board reverse the outstanding rejections, and

that the application be returned to the Examiner for processing in accordance with that reversal.

Please charge the appropriate fee of \$330.00 for filing and consideration of this Appeal Brief to Deposit Account No. 13-3723.

Respectfully submitted,

July 8, 2004

Date

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APPENDIX

PENDING CLAIMS

36. A medical treatment article comprising:
- at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area.
37. The article of claim 36 wherein the article is a wound dressing, wound drain, tympanostomy fluid wick, intravenous access site dressing, drug delivery dressing, surgical drape, or sweat collection patch.
38. The article of claim 36 wherein the remote area comprises a fluid reservoir.
39. The article of claim 36 wherein the channels have a cross-sectional geometry comprising V-shaped channels, rectangular-shaped channels, or a combination V- and rectangular-shaped channels.
40. The article of claim 36 wherein the fluid control film component comprises a plurality of primary channels having at least two secondary channels, each of the secondary channels forming at least one notch, wherein the primary channels have a depth of from 50 to 3000 microns and the depth of the secondary channels is from 5 to 50 percent of the depth of the primary channels.
41. The article of claim 36 wherein the channels have an included angle between about 10 degrees and about 120 degrees.
42. The article of claim 36 wherein the channels are between about 5 and about 3000 microns deep.
43. The article of claim 36 wherein the channels comprise a thermoplastic material selected from the group consisting of polyolefins, polyesters, polyamides, poly(vinyl

chloride), polyether esters, polyimides, polyesteramides, polyurethanes, polyacrylates, polyvinylacetate, hydrolyzed derivatives of polyvinyl acetate and combinations thereof.

44. The article of claim 36 wherein the channels comprise a thermoset material selected from the group consisting of polyurethanes, acrylates, epoxies and silicones.

45. The article of claim 36 wherein the channels comprise a pressure sensitive adhesive material.

46. The article of claim 36 wherein the article is a combined wound dressing and wound drain, and the fluid control film component is adapted to be inserted into the medical treatment site.

47. The article of claim 36 wherein the fluid control film component is adapted to supply a medicament from the fluid reservoir to the medical treatment site.

48. The article of claim 36 further comprising a backing layer positioned to overlie the fluid control film component and the remote area:

wherein the backing layer comprises an adhesive to adhere the article in position for fluid transfer communication with the medical treatment site.

49. The article of claim 36 wherein the article is adapted for visual observation of the site through at least a portion of the fluid control film component.

50. The article of claim 49 wherein the fluid control film component is at least translucent.

51. A method of using a medical article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area, the method comprising:

placing the medical article in proximity to a medical treatment site so that the fluid control film component is capable of providing fluid communication between the medical treatment site and the remote area; and

allowing the medical treatment article to transport fluid between the medical treatment site and the remote area.

52. The method of claim 51 wherein fluid is transported from the medical treatment site to the remote area.

53. The method of claim 52 wherein the remote area comprises a fluid reservoir.

54. The method of claim 53 wherein the fluid reservoir comprises an absorbent material.

55. The method of claim 51 wherein fluid is transported from the remote area to the medical treatment site.

56. The method of claim 52 wherein the fluid comprises a medicament.

57. The method of claim 56 wherein the medicament comprises an antimicrobial, an antiseptic, an analgesic, a vitamin, a steroid, a growth factor, a nutrient, a flushing solution, or any combination of any of the foregoing.

58. The method of claim 51 wherein fluid is transported from the medical treatment site to the remote area and from the remote area to the medical treatment site.

59. The method of claim 51 further comprising visually observing the medical treatment site.

60. The method of claim 59 wherein at least a portion of the medical treatment article is transparent and the step of visually observing the medical treatment article comprises

visually observing the medical treatment site through the transparent portion of the medical treatment article.